

Remarks

This Supplemental Amendment is in response to the Office Action dated September 18, 2009 and in response to Applicants' discussion with the Examiner on November 10, 2009.

Applicants' Representative thanks the Examiner for conducting the phone interview of November 10, 2009. The undersigned attorney discussed possible claim amendments with the Examiner. In light of the discussion during the Examiner interview, Applicants submit herein additional amendments (beyond those in Applicants' Amendment of November 5, 2009) to claims 24 and 31. Additional comments regarding claim 3 are also provided herein.

New claim 32 is herein added. Support for this claim can be found in the Specification at least in paragraphs [0021] and [0043] of the Published Application and in the Application as-filed

In light of the foregoing amendments and following comments, Applicants request allowance of the pending claims.

Claim 3

Claim 3 recites, in part, "said tubular extrude has a bulk density of between 0.2 and 0.5 g/cc." The tubular extrudate comprising non-expanded PTFE (polytetrafluoroethylene) having a density of between 0.2 and 0.5 g/cc provides advantages over known expanded PTFE (ePTFE) materials. For example, the non-expanded porous PTFE tubular extrudate is capable of permitting tissue ingrown into the finished graft product while eliminating the disadvantages of expanded PTFE materials. Specifically, as noted in the Background section of the immediate Application, the porous non-expanded PTFE material is not subject to the drawbacks and expenses associated with manufacturing ePTFE. *See, e.g.,* paragraph [0003] of the Published Application. Moreover, as noted in paragraph [0003], the porosity of an ePTFE graft "will vary in accordance with the fibril length, which for a given expanded structure may have a wide range." These potentially adverse characteristics associated with ePTFE structures are overcome in accordance with the claimed invention. For these reasons, in addition to the reasons provided in Applicants' Amendment of November 5, 2009, claim 3 is believed patentable. As such, Applicants earnestly request allowance of claim 3.

Claims 24 and 31

Claims 24 and 31 are herein amended to remove the term “essentially” from the transitional phrase. As such, amended claims 24 and 31 make use of the transitional phrase “consisting of”.

With regard to the rejection of claim 31 over Dillon (US 4,849,285), Applicants note that Dillon discloses a “particulate ceramic selected from the class consisting of apatite and tricalcium phosphate and particulate sodium chloride.” Column 2, lines 32-34. At least because Dillon discloses the presence of these materials in the composite material thereof, Dillon’s disclosure does not anticipate or render obvious the immediate claims.

With respect to the rejection of claim 24 over Freiburger (H1978), and as discussed in Applicants’ Amendment of November 5, 2009, Frieburger does not teach or suggest a tubular extrudate, as is claimed. As shown above, claim 24 has been amended to positively recite “an interpenetrating polymer network comprising a non-expanded PTFE resin formed in the shape of a tube. . . .”

Moreover, Freiburger does not teach or suggest a tubular graft consisting of “discrete domains of said polymeric component [that] are distributed throughout said non-expanded PTFE resin and are extractable therefrom to create pores in said PTFE resin”

At least in light of the foregoing, claims 24 and 31 are believed to be in condition for allowance. Applicants earnestly request allowance of these claims.

Claim 32

Claim 32 is herein added. Claim 32 recites:

32. (New) A PTFE based tubular graft comprising:
a porous tubular graft, wherein the porous tubular graft is formed of porous PTFE which has been subjected to expansion and sintering wherein the porous tubular graft is characterized as having a density of less than 0.2 g/cc.

Support for this claim can be found in paragraphs [0021] and [0043] of the Published Application and in the Application as-filed. Additionally, it is noted that expansion of the already porous PTFE decreases its density. Thus, claim 32 is supported by the Application as filed.

The PTFE based tubular graft of claim 32 is further believed to provide advantages over ePTFE that is not formed of porous PTFE. For instance, the claimed PTFE based tubular graft will provide for increased endothelialization over traditional grafts made of ePTFE that was not porous prior to expansion. Moreover, the claimed PTFE graft can have two types of porosity. Certain pores can have a pore size attributable to the initial porosity of the PTFE, for example, from the removal of extractable polymer, while other pores have a pore size determined by the amount of expansion due to stretching of the porous PTFE. Larger pore size generally corresponds to increased flexibility, while smaller pore size generally corresponds to increased integrity. A typical ePTFE graft made from non-porous PTFE would not be expected to have the additional degree of porosity associated with the claimed graft.

In light of the foregoing comments and the belief that none of the cited references teach or suggest what is claimed in independent claim 32, Applicants request allowance of new claim 32.

Conclusion

Based on at least the foregoing remarks, Applicants requests withdrawal of the rejections and allowance of claims 2, 3, 21, 22, 24, and 27-32. Favorable consideration and prompt allowance of these claims is earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

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